

National Institutes of Health

Summary of the FY 2005 President's Budget



February 2, 2004

NIH Budget at a Glance

		<u>Change</u>
FY 2003 Actual	\$27,173 M	
FY 2004 Enacted Level	\$28,028 M	3.1%
FY 2005 President's Budget - Budget Authority	\$28,757 M	2.6%
Number of Competing RPGs	10,393	+258 over FY 2004
Total Number of RPGs w/o SBIR/STTR	37,744	+515 over FY 2004

Over the last half century, the nation's investment in the NIH yielded myriad scientific achievements, many of which improved the length and quality of human life. Many more of these publicly funded research efforts are the basis for countless future advances in science and improvements in health. One of the most visible examples, the completion of the sequencing of the human genome, is creating heretofore un-imagined opportunities to explore the full spectrum of human biology in both health and disease.

To build on past accomplishments, further accelerate the pace of scientific discovery, and spur the translation of findings into newer and even better ways to prevent, diagnose, and treat disease, in September 2003, NIH leadership launched a set of initiatives collectively known as the NIH Roadmap for Medical Research. The NIH Roadmap targets research investments that promise to yield far-reaching dividends in medical knowledge. The initiatives cut across the missions of Institutes and Centers, integrate the work of multiple disciplines, and are expected to lead to advancements that address the most pressing health needs and medical concerns of the American people.

Aware of the significant shift of disease burden that has taken place in recent decades, NIH is increasingly focused on chronic diseases, which have overtaken acute conditions as the nation's leading killers – conditions such as cardiovascular disease, stroke, hypertension, and cancer. NIH will also expand a major NIH-wide initiative begun last year to uncover the knowledge needed to prevent and treat one of the nation's most pressing health problems – obesity. The NIH also remains focused on reducing or eliminating health disparities among racial, ethnic, and disadvantaged populations.

The NIH will continue efforts to protect the Nation against potentially lethal bioterrorist acts through basic research on the infectious diseases that constitute the highest threats and developing vaccines, diagnostics, and therapeutics to address them. We will also maintain a strong focus on other infectious diseases that threaten the health of the nation, such as SARS, West Nile Virus, influenza, malaria, and tuberculosis as well as the persistent problem of HIV/AIDS.

As the most influential force in the U.S. biomedical research community, NIH exercises its leadership by continually surveying public health needs and the scientific landscape to identify

new biomedical areas that require attention and new opportunities for progress. To maintain the vibrancy of our nation's scientific enterprise, NIH also actively supports strong basic and clinical research training programs. NIH-funded programs are unique in both igniting and complementing private sector research and development efforts. NIH tackles studies for which the risks are too high or the fiscal incentives too low to attract private investment. These research arenas span the health care spectrum, ranging from basic studies and technology development to the evaluation of non-commercially viable, yet critical, lifestyle interventions such as modified diet and exercise. Tailoring therapies for the special needs of vulnerable populations and evaluating treatments for rare diseases are other NIH-led investigations where the intervention of a public agency is essential. With the massive responsibility of advancing knowledge across such a wide landscape, whenever possible, NIH marshals efforts of industry, research organizations, disease foundations, and patient groups to maximize its efforts.

NIH supports an extramural research community of an estimated 212,000 research personnel who are affiliated with approximately 2,800 organizations, including universities, medical schools, hospitals, and other research facilities in all 50 states as well as the District of Columbia, Puerto Rico, Guam, the Virgin Islands, and international venues. NIH's 27 Institutes and Centers are based at the world's largest campus for biomedical research, where an in-house (intramural) research enterprise is staffed by a cadre of distinguished clinicians and scientists. This intramural program will utilize the nearly completed state-of-the-art Clinical Research Center, providing the nation and the world with an unparalleled capacity for rapid response to serious health challenges.

To maintain a research portfolio that balances public health needs and scientific opportunities, NIH seeks public input through multiple channels, including the Advisory Committee to the Director and the NIH Council of Public Representatives. A two-tier system of advisory bodies and specialized review committees guarantees funding of the best applications from among the nearly 50,000 research and training applications reviewed annually. The general public has direct access to a wealth of reliable and readily understandable health information through a variety of NIH contact points, including the very popular NIH web site (www.nih.gov). Also featured at this site are ongoing clinical studies, which underscore NIH's commitment to translate research discoveries into treatment strategies for use by physicians on the front lines.

The FY 2005 program level for the NIH is \$28,805 million, an increase of \$764 million or 2.7 percent over the FY 2004 Enacted Level. The NIH's President's Budget authority request to the Labor/Health and Human Services/Education Appropriations Subcommittee is \$28,527 million. The budget authority request to the Veteran's Administration/Housing and Urban Development, and Independent Agencies Appropriations Subcommittee is \$80.5 million for the NIEHS Superfund research program. The NIH program level also includes \$150 million for the Type I Diabetes Initiative appropriated by Public Law 107-360. Of this program total, \$47.4 million is included in the budget authority request of the Public Health and Social Services Emergency Fund (PHSSEF), for research in radiological/nuclear countermeasures.

NIH Roadmap for Biomedical Research

The NIH Roadmap is the result of an ongoing series of consultations with scientists charged with thinking broadly about the future. It comprises three broad initiatives that will exploit and extend past discoveries to meet tomorrow's challenges:

- New Pathways to Discovery: \$137 million. These NIH Roadmap initiatives focus on generating new knowledge and building a better "toolbox" for researchers in the 21st century, including new technologies, databases, and other resources.
- Multidisciplinary Research Teams of the Future: \$39 million. The scale and complexity of today's biomedical research problems increasingly demands that scientists move beyond the confines of their own discipline and explore new organizational models for team science. This set of NIH Roadmap initiatives establishes a series of awards for centers and training, as well as support for conferences aimed at building interdisciplinary research teams.
- Re-engineering the Clinical Research Enterprise: \$61 million. This set of NIH Roadmap initiatives aims to organize and support a new infrastructure that will facilitate the rapid translation of discoveries from the laboratory to the clinic; train a workforce of clinical investigators to test new therapeutic and preventive strategies; create clinical research networks with enhanced interoperability; and enhance the coordination of the important rules and regulations that ensure the safety and ethics of these studies.

In FY 2005, NIH will direct \$237 million toward these Roadmap initiatives, an increase of \$109 million over FY 2004. \$60 million will be provided by the NIH Director's Discretionary Fund (DDF), and the remaining \$177 million will be provided by the Institutes and Centers (ICs). The IC contribution to support these trans-NIH research goals will represent 0.63 percent of each individual budget request for FY 2005.

Obesity

The epidemic of obesity threatens the Nation's health by sharply increasing the incidence of type 2 diabetes, fatty liver disease, kidney failure, and cardiovascular and other diseases. However, dramatic advances in our understanding of regulation of appetite and weight offer new opportunities to develop methods to treat obesity and to prevent type 2 diabetes and other obesity-related diseases.

To coordinate and accelerate its obesity research efforts, NIH has created an Obesity Research Task Force. With the assistance of external scientific and public advisors, the Task Force is developing a strategic plan for NIH obesity research. The FY 2005 President's Budget includes \$22 million for expanded trans-NIH research programs in obesity and diabetes, with the distribution following the priorities of the Obesity Task Force:

- Prevention and Treatment of Childhood Obesity in Primary Care Settings (\$3.5 million).
- Site-Specific Approaches to Prevention and Treatment of Pediatric Obesity (\$3.5 million).
- Neurobiological Basis of Obesity (\$6.0 million).

- Bioengineering Approaches for Prevention and Treatment of Overweight and Obesity. (\$2.0 million).
- Obesity and the Built Environment program (\$1.0 million).
- Obesity Clinical Research Center (OCRC) (\$6.0 million).

Biodefense

Planned new and expanded biodefense initiatives in FY 2005 will include the following major milestones and activities:

- Complete the establishment of the extramural Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCE). These centers will be based regionally and will form the heart of the extramural research activities in their geographical area. Each center will provide support to researchers by making available specialized equipment and tools, including the specialized laboratories required; providing specialized knowledge and expert advice; and conducting specialized training.
- Initiate the second phase of construction of specialized, biosafety research laboratories for extramural researchers. These specialized research laboratories, at the BSL-3 and -4 levels, are necessary to conduct research on the highly dangerous and infectious pathogens in the biodefense research field. The laboratories are a critical component of the planned network of extramural RCEs.
- Undertake the clinical trials of plague, Ebola, and tularemia vaccine candidates.

AIDS

Consistent with the development of the NIH non-Biodefense research budget, the AIDS research program will increase by 2.8 percent or \$80 million, for a total of \$2,930 million.

Mechanism Discussion

The funding of basic biomedical research through investigator-initiated research, including Research Project Grants (RPGs), and the support of new researchers with new ideas are the highest priorities for the National Institutes of Health. The FY 2005 request would support an estimated 10,393 competing RPGs, for \$3,609 million, an increase of 258 competing RPGs over the FY 2004 Enacted Level estimate of 10,135 competing RPGs.

The FY 2005 President's Budget provides an aggregate 1.3 percent increase in average cost for Research Project Grants, consistent with the Gross Domestic Product deflator. Within this 1.3 percent aggregate increase, NIH is providing average cost increases of 1.9 percent for direct recurring costs in noncompeting continuation awards; competing RPGs receive an average cost increase of 1 percent.

Stipends for pre-doctoral and post-doctoral recipients of the Ruth L. Kirschstein National Research Service Awards will remain at FY 2004 levels. The total increase in Research Training is \$15 million, or 2 percent.

Included in the Buildings and Facilities mechanism of support is \$8 million provided to the National Cancer Institute (NCI). As part of NIH's ongoing review of its facilities program and management processes, it was determined that NCI should request specific authorization to undertake repairs and improvements at the NCI-Frederick campus operated as a Federally-funded Research and Development Contract (FFRDC). The request for this authority is included in the NCI budget request for FY 2005.

The Office of the Director (OD) increases by \$33 million, or 10 percent. Of this amount, \$60 million has been reserved in the NIH Director's Discretionary Fund for allocation to Roadmap activities. Another \$10 million is available in the DDF for non-Roadmap projects, making a total for the DDF \$70 million in the FY 2005 request. The increase for the OD excluding Roadmap funding is \$12 million or 4.2%.

Other Key Issues

Radiological and Nuclear Countermeasures

The use of a nuclear or radiological device in a terrorist attack presents a critical challenge to the United States. The most plausible terrorist radiological or nuclear scenarios envision situations that are more limited in scope and in which the health effects of radiation exposure could be mitigated by intensive medical intervention. However, it is also clear that little progress has been made during the last forty years to improve the medical management of injuries produced by radiation.

In FY 2005, NIH will therefore initiate a research effort that will focus on the development of three kinds of medical interventions:

- the development of drugs that can be used to prevent injury from radiological exposure;
- improved methods of measuring radiological exposure and contamination (biodosimetry); and
- the development of methods/drugs to restore injured tissues and eliminate radioactive materials from contaminated tissues (i.e., drugs that could scavenge radionuclides from tissues).

The Department of Health and Human Services (HHS) has requested that \$47.4 million be provided in FY 2005 to support specific targeted research activities needed to develop radiological and nuclear threat countermeasures. While NIH would manage and oversee this work, these funds are budgeted in the Public Health and Social Services Emergency Fund (PHSSEF). Placing these funds in the PHSSEF enables them to be appropriated in one place, as with some other biodefense funds in the DHHS, and then allocated to the proper NIH Institutes or Centers to implement the targeted activities.

NIH Management

To further NIH's scientific agenda, the agency's management and administration must be effective and efficient. From the introduction of new information technology and business systems, to the streamlining of governance structures and the development of a new approach to portfolio management, continual improvement of management and administrative functions is at the forefront of NIH agency priorities. A few highlights of these efforts are described below.

NIH is making rapid progress to modernize its business and financial systems. An agency-wide information technology system, known as the New Business System (NBS), is integrating processes such as acquisitions, travel, property, and financial management reducing the cost and complexity of doing business, increasing service levels, and improving management controls. NBS serves as a proof of concept for, and a major element of, the DHHS Unified Financial Management System. As both systems mature, the NBS will merge into the single financial management system envisioned by DHHS.

As the NIH has grown in size and complexity, there has been an increased focus on a more efficient means of trans-NIH coordination. To create a more agile means by which the Agency makes administrative management decisions, the NIH Director formed the NIH Steering Committee. The committee is chaired by the NIH Director and made up of a rotating membership of 10 Directors representing the 27 NIH Institutes and Centers (ICs). While the NIH Director and IC Directors will continue to formulate their specific scientific directions and priorities as well as operational oversight of their respective institutes and centers, the Steering Committee will focus on NIH-wide policies and important operational decisions.

NIH continues to make progress on its restructuring activities, including those in support of the DHHS "One Department" goals and the Presidential Management Agenda. Earlier this year, the NIH Director created an Administrative Restructuring Advisory Committee (ARAC) to review the following NIH administrative functions: Acquisition, Finance, Budget, Grants Management, Facilities, Equal Employment Opportunity, Information Technology and Human Resources. Sub-committees were established to review each separate function, and reported back to the ARAC. The ARAC report recommendations are in the process of being implemented, which will further improve the efficiency of NIH administrative operations.

In FY 2003, more than 1,000 FTEs were placed under A-76 review— including extramural administrative support to program, review and grants management, and real property management. NIH won the Grants Administration competition and the Real Property Management competition. Plans are underway to implement the Most Effective Organization for these functions in the spring, 2004. Consistent with the Department's commitment that affected employees will have a job, NIH will be using all tools at its disposal to retrain, counsel, and place affected employees within NIH, DHHS, other Federal agencies or alternate employers.

The NIH budget doubled in the five years from FY 1999 through FY 2003. The agency entered the post doubling period far stronger and better positioned to improve health through advances in research. New insights into human biology and behavior are bringing us closer to prevention

strategies and treatments for many of the most dreaded diseases and conditions. The NIH portfolio is broader and deeper making us better prepared to handle unexpected health crises; and NIH systems of management and administration are being strengthened to better serve the public and medical science. The trust and responsibility placed in NIH will be honored and met with innovations that lead to substantive improvements in health.

NATIONAL INSTITUTES OF HEALTH

Summary of Appropriations

(Dollars in millions)

Appropriation	FY 2003 Budget Authority 1/2/3/4/	FY 2004 Enacted 1/5/6/	FY 2005 Estimate 1/
	Includes AIDS	Includes AIDS	Includes AIDS
NCI 7/	\$4,586	\$4,736	\$4,870
NHLBI	2,792	2,878	2,964
NIDCR	371	383	394
NIDDK	1,721	1,821	1,876
NINDS	1,455	1,501	1,546
NIAID	3,703	4,303	4,425
NIGMS	1,847	1,905	1,960
NICHD	1,204	1,242	1,281
NEI	632	653	671
NIEHS	612	631	650
NIA	993	1,025	1,056
NIAMS	486	501	515
NIDCD	370	382	393
NIMH	1,339	1,381	1,421
NIDA 8/	965	991	1,019
NIAAA	416	428	442
NINR	130	135	139
NHGRI	464	479	493
NIBIB	280	289	298
NCRR	1,139	1,179	1,094
NCCAM	113	117	121
NCMHD	186	191	197
FIC	62	65	67
NLM	298	308	325
OD 9/	286	327	360
B&F	639	99	100
Type 1 Diabetes 10/	-100	-150	-150
Subtotal, Labor/HHS	26,989	27,800	28,527
VA/HUD Approp.	84	78	80
Total, NIH Discretionary B.A.	27,073	27,878	28,607
Type 1 Diabetes 10/	100	150	150
Total, NIH Budget Authority	27,173	28,028	28,757
NLM Program Evaluation	8	8	0
ONDCP	0	5	0
PHSSEF	0	0	47
Total, Prog. Level	27,181	28,041	28,804

1/ Includes funds to be transferred to the Global Fund for HIV/AIDS,

Tuberculosis and Malaria (FY 2003 - \$99.350 million; FY 2004 - \$149.115 million; FY 2005 - \$100.0 million)

2/ Reflects across-the-board reduction of -\$177.085 million.

3/ Reflects transfer of -\$583,000 to the Department of Homeland Security.

4/ Comparable for transfers to NIBIB, OD, and B&F, and from FIC. Comparable for transfer to DHHS for Public Health Reports

5/ Reflects across-the-board reduction of -\$164.459 million, and Labor/HHS/Ed reduction of -\$17.492 million.

6/ Comparable for transfers to NIBIB and B & F. Comparable for transfer to DHHS for Public Health Reports (-\$70,000).

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Budget Mechanism - Total

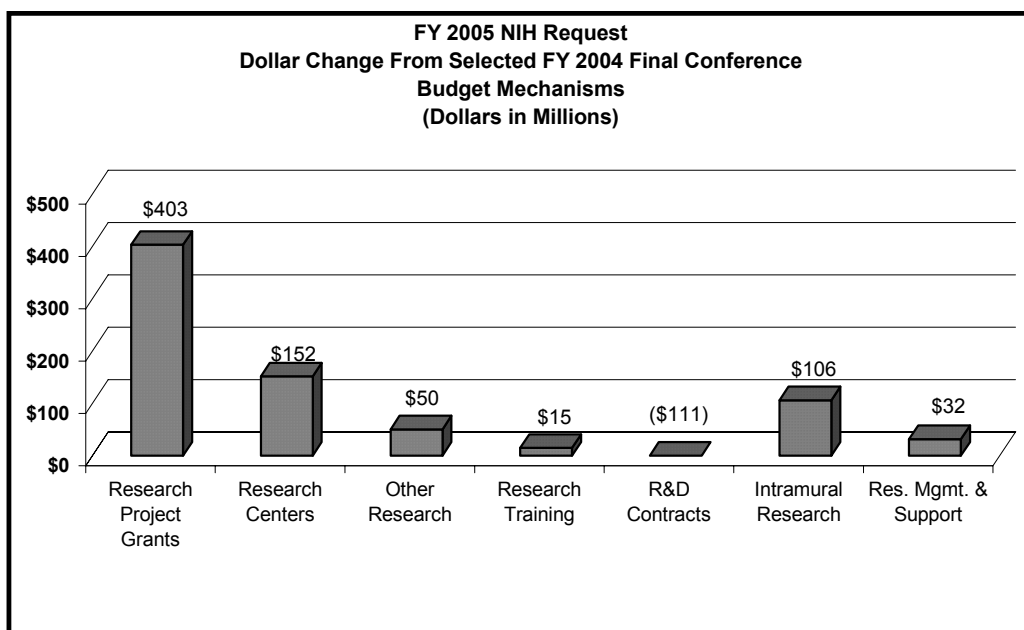
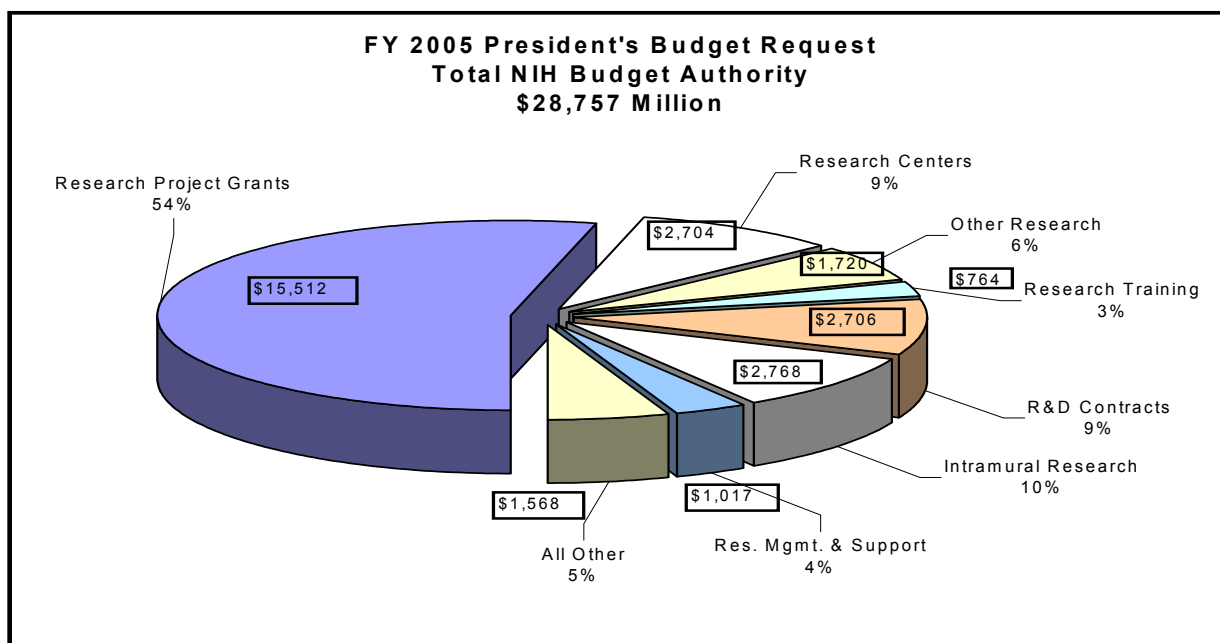
(Dollars in Millions)

MECHANISM	FY 2003 Actual 1/		FY 2004 Final Conference		FY 2005 Estimate		2005/2004 % Change	Change	
	No.	Amount	No.	Amount	No.	Amount		No.	Amount
Research Grants:									
Research Projects:									
Noncompeting	25,757	\$9,987	27,094	\$10,794	27,351	\$11,099	2.8	257	\$305
Administrative supplements	(2,016)	198	(1,673)	173	(1,761)	185	6.9	88	12
Subtotal, competing	10,393	3,519	10,135	3,540	10,393	3,609	1.9	258	69
Subtotal, RPGs	36,150	13,704	37,229	14,507	37,744	14,893	2.7	515	386
SBIR/STTR	2,020	538	2,199	602	2,242	618	2.7	43	16
Subtotal, RPGs	38,170	14,242	39,428	15,109	39,986	15,511	2.7	558	402
Research Centers:									
Specialized/comprehensive	1,011	1,833	1,016	1,938	1,032	2,063	6.4	16	125
Clinical research	106	285	106	296	106	304	2.7	0	8
Biotechnology	78	143	98	145	98	155	6.9	0	10
Comparative medicine	53	109	63	116	64	123	6.0	1	7
Research Centers in Minority Institutions	18	56	18	57	18	59	3.5	0	2
Subtotal, Centers	1,266	2,426	1,301	2,552	1,318	2,704	6.0	17	152
Other Research:									
Research careers	4,058	536	4,318	577	4,457	598	3.6	139	21
Cancer education	102	30	104	31	106	32	3.2	2	1
Cooperative clinical research	387	379	418	393	422	404	2.8	4	11
Biomedical research support	177	120	179	136	179	143	5.1	0	7
Minority biomedical research support	168	117	174	121	174	122	0.8	0	1
Other	1,487	405	1,546	411	1,607	420	2.2	61	9
Subtotal, Other Research	6,379	1,587	6,739	1,669	6,945	1,719	3.0	206	50
Total Research Grants	45,815	18,255	47,468	19,330	48,249	19,934	3.1	781	604
Ruth L. Kirschstein Training Awards:	FITPs		FITPs		FITPs				
Individual awards	2,773	108	2,779	112	2,785	113	0.9	6	1
Institutional awards	14,533	603	14,787	637	15,006	651	2.2	219	14
Total, Training	17,306	711	17,566	749	17,791	764	2.0	225	15
Research & development contracts (SBIR/STTR)	2,518 (99)	2,399 (22)	2,572 (102)	2,817 (23)	2,630 (103)	2,706 (25)	-3.9	58	(111)
	FTEs		FTEs		FTEs				
Intramural research	6,874	2,547	6,728	2,662	6,724	2,768	4.0		106
Research management and support	4,260	921	4,389	986	4,381	1,017	3.1		31
Cancer prevention & control	469	531	438	545	438	545	0.0		0
Extramural Construction		495		119		150	26.1		31
Library of Medicine	690	298	663	308	665	325			
Office of the Director	598	286	598	327	604	360			
Buildings and Facilities 2/		646		107		108			
Type 1 Diabetes 3/		-100		-150		-150			
Subtotal, Labor/HHS Budget Authority		26,989		27,800		28,527	2.6		727
VA/HUD Appropriation		84		78		80			2
Total, NIH Discretionary B.A.		27,073		27,878		28,607	2.6		729
Type 1 Diabetes 3/		100		150		150			0
Total, NIH Budget Authority		27,173		28,028		28,757	2.6		729
NLM Program Evaluation		8		8		0			(8)
ONDCP		0		5		0			(5)
PHSSEF Nuclear Radiological Research		0		0		47			47
Total, Program Level		27,181		28,041		28,804	2.7		763
(RoadMap Support)		(16)		(128)		(237)	85.2		(109)
(Clinical Trials)		(2,723)		(2,875)		(2,998)	4.3		(123)

1/ Budget Authority 2003 total includes \$4,000,000 ONDCP transfer; NCI breast cancer stamp funds of \$3,130,000.

2/ Includes the B&F appropriation plus the following included in NCI -- FY 03: \$7,800,000; FY 04: \$8,000,000; FY 05: \$8,000,000.

3/ Included in NIDDK -- FY 03: \$100,000,000; FY 04: \$150,000,000; FY 05: \$150,000,000.



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NIH Roadmap
(dollars in millions)

Title of Initiative	Lead Administrative ICs	FY 2004 Funding	FY 2005 Funding
<i>New Pathways of Discovery</i>			
Molecular Libraries and Imaging			
Creation of NIH Bioactive Small Molecule Library & Screening Centers	NIMH, NHGRI	\$15.0	\$38.5
Cheminformatics	NHGRI, NLM	5.0	7.5
Technology Development	NIGMS, NINDS, NHGRI, NIBIB	6.5	13.0
Development of High Resolution Probes for Cellular Imaging	NIGMS	1.3	5.0
Imaging Probe Database	NCI	1.0	1.3
Core Synthesis Facility to Produce Imaging Probes	NHLBI	3.0	2.0
<i>Subtotal, Molecular Libraries and Imaging</i>		<i>31.8</i>	<i>67.3</i>
Building Blocks, Biological Pathways and Networks			
Metabolomics Technology Development	NIDDK, NCRR	14.8	29.1
Standards for Proteomics and Metabolomics	NCRR, NIDDK, NHGRI	0.2	0.2
<i>Subtotal, Building Blocks, Biological Pathways and Networks</i>		<i>15.0</i>	<i>29.3</i>
Structural Biology			
Centers for Innovation in Membrane Protein Production	NIGMS	5.0	10.0
Bioinformatics and Computational Biology			
National Centers for Biomedical Computing	NIGMS	12.0	24.0
Nanomedicine			
Conceptual Planning for Nanomedicine Development Centers	NEI	0.0	0.0
Nanomedicine Development Centers	NEI	0.3	0.0
<i>Subtotal, Nanomedicine</i>		<i>0.0</i>	<i>0.0</i>
<i>Subtotal, New Pathways of Discovery</i>		<i>64.1</i>	<i>136.6</i>
<i>Research Teams of the Future</i>			
Interdisciplinary Research			
Interdisciplinary Research Centers	NCRR	9.0	9.0
Interdisciplinary Research Training Initiative	NIDDK, OBSSR, NIGMS	10.1	17.2
Innovation in Interdisciplinary Technology and Methods	OD/OBSSR	1.0	1.0
Removing Structural Barriers to Interdisciplinary Research	CSR, OD/OER	0.0	0.0
Using the NIH Intramural Research Program as a Model for Interdisciplinary	OD/OIR	0.0	0.0
Interagency Conference on the Interface of Life Sciences and Physical Sciences	NIDCR	0.1	0.0
<i>Subtotal, Interdisciplinary Research</i>		<i>20.2</i>	<i>27.2</i>
High-risk Research			
NIH Director's Pioneer Awards	OD	5.9	11.3
		0.0	0.0
Public-Private Partnerships			
Designation of a Central Point of Contact	OD	0.0	0.0
High-Level Science Driven Partnership Meetings	OD	0.5	0.5
		0.0	0.0
<i>Subtotal, Public Private Partnerships</i>		<i>0.5</i>	<i>0.5</i>
<i>Subtotal, Research Teams of the Future</i>		<i>26.6</i>	<i>39.1</i>
<i>Re-engineering the Clinical Research Enterprise</i>			
Clinical Research Policy Analysis and Coordination	OD/OSP	2.0	2.9
Feasibility of Integrating and Expanding Clinical Research Networks	NHLBI	18.0	18.5
Translational Research Core Services	NIDDK	0.4	2.4
Dynamic Assessment of Patient-Reported Chronic Disease Outcomes	NIAMS	5.0	5.0
Regional Translational Research Centers	NCCAM	0.3	3.4
Enhance Clinical Research Training via the National Multi-disciplinary CR Career	NICHD, OD/OIR, NICHD	9.2	28.9
Create a National Clinical Research Associates Program	NICHD	2.8	0.0
<i>Subtotal, Re-engineering the Clinical Research Enterprise</i>		<i>37.6</i>	<i>61.1</i>
Total Roadmap		128.3	236.8